

Food and Drug Administration, HHS

§ 330.10

(75) “You” (“Your”) or “the child” (“the child’s”).

(76) “You also have” or “occurs with”.

(77) “When practical” or “if possible”.

(78) “Whether” or “if”.

(79) “Worsen(s)” or “get(s) worse” or “make(s) worse”.

(j) The following connecting terms may be deleted from the labeling of OTC drug products, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the specific title, headings, and sub-headings required under §201.66(c)(1) through (c)(9) of this chapter:

(1) “And”.

(2) “As may occur with”.

(3) “Associated” or “to be associated”.

(4) “Consult a doctor”.

(5) “Discontinue use”.

(6) “Drug Interaction Precaution”.

(7) “Due to”.

(8) “Except under the advice and supervision of a physician”.

(9) “If this occurs”.

(10) “In case of”.

(11) “Notice”.

(12) “Or”.

(13) “Occurring with”.

(14) “Or as directed by a doctor”.

(15) “Such as”.

(16) “Such as occurs with”.

(17) “Tends to”.

(18) “This product”.

(19) “Unless directed by a doctor”.

(20) “While taking this product” or “before taking this product”.

(21) “Within”.

[39 FR 11741, Mar. 29, 1974, as amended at 40 FR 11718, Mar. 13, 1975; 40 FR 13496, Mar. 27, 1975; 42 FR 15674, Mar. 22, 1977; 46 FR 8459, Jan. 27, 1981; 50 FR 8996, Mar. 6, 1985; 51 FR 16266, May 1, 1986; 55 FR 11581, Mar. 29, 1990; 59 FR 4000, Jan. 28, 1994; 59 FR 14365, Mar. 28, 1994; 64 FR 13294, Mar. 17, 1999]

§ 330.2 Pregnancy-nursing warning.

A pregnancy-nursing warning for OTC drugs is set forth under §201.63 of this chapter.

[47 FR 54753, Dec. 3, 1982]

§ 330.3 Imprinting of solid oral dosage form drug products.

A requirement to imprint an identification code on solid oral dosage form drug products is set forth under part 206 of this chapter.

[58 FR 47959, Sept. 13, 1993]

§ 330.5 Drug categories.

Monographs promulgated pursuant to the provisions of this part shall be established in this part 330 and following parts and shall cover the following designated categories:

- (a) Antacids.
- (b) Laxatives.
- (c) Antidiarrheal products.
- (d) Emetics.
- (e) Antiemetics.
- (f) Antiperspirants.
- (g) Sunburn prevention and treatment products.
- (h) Vitamin-mineral products.
- (i) Antimicrobial products.
- (j) Dandruff products.
- (k) Oral hygiene aids.
- (l) Hemorrhoidal products.
- (m) Hematinics.
- (n) Bronchodilator and antiasthmatic products.
- (o) Analgesics.
- (p) Sedatives and sleep aids.
- (q) Stimulants.
- (r) Antitussives.
- (s) Allergy treatment products.
- (t) Cold remedies.
- (u) Antirheumatic products.
- (v) Ophthalmic products.
- (w) Contraceptive products.
- (x) Miscellaneous dermatologic products.
- (y) Dentifrices and dental products such as analgesics, antiseptics, etc.
- (z) Miscellaneous (all other OTC drugs not falling within one of the above therapeutic categories).

Subpart B—Administrative Procedures

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not